U.S. Food and Drug Administration Extends Action Date for Inhaled Treprostinil (Tyvaso) New Drug Application by Three Months

SILVER SPRING, Md., April 28, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- United Therapeutics Corporation (Nasdaq: UTHR) announced today that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of the New Drug Application (NDA) for Tyvaso(TM) (inhaled treprostinil). In a notice received today, the FDA extended the Prescription Drug User Fee Act (PDUFA) date from April 30, 2009, to July 30, 2009. United Therapeutics previously disclosed the likelihood of this delay in a press release dated March 16, 2009.

The three-month extension was triggered by United Therapeutics' April 2009 submission to the FDA of the results of a human factors study, which was considered a major amendment to the NDA. In March 2009, the FDA notified United Therapeutics that it required human factors testing to validate the instructions for use of the Optineb(R) nebulizer in order to complete its evaluation of the Tyvaso NDA. "We look forward to working with the FDA as it completes its review of our human factors study submission," said Roger Jeffs, Ph.D., United Therapeutics' President and Chief Operating Officer. "We made every effort to conduct and submit the study as quickly as possible."

"We are most appreciative of the FDA's input as we work toward our goal of bringing Tyvaso to market," said Martine Rothblatt, Ph.D., United Therapeutics' Chairman and Chief Executive Officer. "This news will provide considerable hope to the thousands of pulmonary hypertension patients struggling with existing treatments."

About United Therapeutics

United Therapeutics Corporation is a biotechnology company focused on the development and commercialization of unique products to address the unmet medical needs of patients with chronic and life-threatening cardiovascular and infectious diseases and cancer.

Forward-looking Statements

Statements included in this press release concerning the FDA's pending review of our Tyvaso NDA, the expected duration of such review and our goal of bringing Tyvaso to market are "forward-looking statements" within the meaning of the safe harbor contained in the Private Securities Litigation Reform Act of 1995. These forward-looking statements are qualified by the cautionary statements, cautionary language and risk factors set forth in our periodic reports and documents filed with the Securities and Exchange Commission, including our most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and current reports on Form 8-K, which could cause actual results to differ materially from anticipated results. We are providing this information as of April 28, 2009, and assume no obligation to update or revise the information contained in this press release whether as a result of new information, future events or any other reason. [uthr-g]

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